

Remarks

This Amendment and the concurrently filed Request for Continued Examination are in response to the Advisory Action dated **December 11, 2006**.

Applicant notes with appreciation that the Office has removed the rejections to claims 25 and 26.

The Office maintained the previous rejections of claims 1-6, 11-12, 14, 22, and 64-67 under 35 USC 102(e), alleging the same as being anticipated by U.S. Patent No. 6,296,655 to Gaudoin et al. ("Gaudoin").

Claims 7 – 9 and 28 – 29 were objected to as being dependent upon a rejected base claim, but were said to contain allowable subject matter.

The following comments are presented in the same order and with headings and paragraph numbers corresponding to the rejections set forth in the Office Action.

Claim Rejections—35 U.S.C. § 102

2. Claims 1-6, 11-12, 14, 22, and 64-67 are rejected under 35 USC 102(e) as being anticipated by Gaudoin. The Office Action, referencing FIGs. 7-8 of Gaudoin, maintains that Gaudoin discloses "a plurality of inflatable members (25)" which do not encircle the channel. Applicant respectfully disagrees with the rejection for the reasons presented below.

Claim 1, and claims 2, 3, 4, 6, 11, 12, and 22 which depend therefrom are patentable over Gaudoin

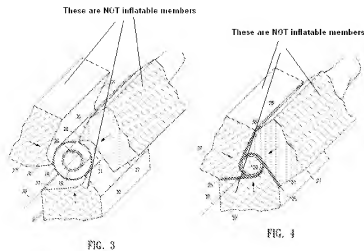
Claim 1 has been amended to recite that the plurality of inflatable members are disposed about the channel and configured to contain at least a portion of an inflatable balloon of a balloon catheter within the channel. Claim 1 has also been amended to recite the presence of a housing configured to constrain the plurality of inflatable members. Claim 1 and its dependent claims are patentable over Gaudoin for the following reasons:

1. Gaudoin Does Not Have Inflatable Members For Configuring An Inflatable Balloon

First, Applicant's *limiting preamble* claims a device for configuring an inflatable balloon. Applicant's device for configuring an inflatable balloon comprises a plurality of

inflatable members 116 used to configure an inflatable balloon 104.

The Gaudoin device for configuring an inflatable balloon, however *does not have a plurality of inflatable members*. Figures 3 and 4 of Gaudoin are presented below:



Gaudoin uses “elongated shaping tools 27”, “each having planar surfaces 30 and 31”. There is no teaching or suggestion in Gaudoin to use inflatable members for the elongate shaping tools. to configure an inflatable balloon. Thus, because Gaudoin does not teach or suggest all the elements of claim 1, Gaudoin is not anticipatory.

2. The Channel Recitation Is Not Met By Gaudoin

Claim 1 and its dependent claims include the recitation that a plurality of inflatable members defining a channel therebetween. The plurality of inflatable members are disposed about the channel and configured to contain at least a portion of an inflatable balloon of a balloon catheter within the channel. Each inflatable member has a balloon contacting portion. Each inflatable member extends part of the way about the channel but does not encircle the channel.

This feature is not met by Gaudoin. The Examiner has asserted that the wings of Gaudoin are inflatable members and that they meet the claim recitation. First, the three Gaudoin wings do not define ‘a channel’. To the extent that there is a channel in the center of the Gaudoin balloon, it is defined by the portions of the Gaudoin balloon (ie one inflatable member) which extend in a circumferential direction and not by the wings. There is no disclosure that these

portions of the Gaudoin balloon are configured to contain at least at least a portion of an inflatable balloon of a balloon catheter. Finally, there is no disclosure that the Gaudoin balloon has ‘balloon contacting portions’. Even if one were able to insert a balloon portion of a balloon catheter in the Gaudoin channel, the balloon of Gaudoin would not contact the balloon portion – it would be blocked from contact by the catheter upon which the Gaudoin balloon is mounted.

Second, assuming for the sake of argument that the each wing of Gaudoin can be considered an inflatable member, the “plurality of inflatable members do not define a channel therebetween,” with each inflatable member extending “part of the way about the channel but does not encircle the channel,” as recited in claim 1. A **modified** version of FIG. 6 of Gaudoin is presented below:

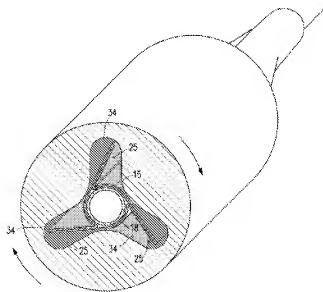


FIG. 6

The darker gray spaces above are not a channel which is defined **between** a plurality of inflatable members. Each darker gray space “channel” in FIG. 6 is defined between a single wing and a portion of the die 33 (reference number 33 appears in FIG. 7 but was omitted in FIG. 6) and not between a plurality of ‘inflatable members’, as recited in claim 1. Similarly, the lighter gray spaces above are also not a channel which is defined **between** a plurality of inflatable members. Each lighter gray space “channel” in FIG. 6 is defined between a wing and a portion of the die 33 and region 18 and not between a plurality of inflatable members, as recited in claim 1.

This is in contrast to the instant case, as shown below in FIG. 14, for example:

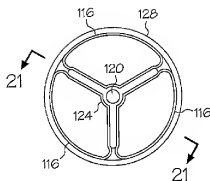


FIG. 14

As seen in FIG. 14, the plurality of inflatable members 116 define channel 120.

Moreover, the claim recitation “each inflatable member extends part of the way about the channel but does not encircle the channel” requires that *all* of the inflatable members extend part of the way about the channel. Assuming for the sake of argument that the die 33 does not define a portion of a channel, the above-quoted limitation of claim 1 is not met by either the darker gray spaces or the lighter gray spaces because for a given darker gray or lighter gray space, there is at least one “inflatable member” as identified by the Office Action which does not extend part of the way around the darker gray or lighter gray space. That is, at best, only two of the three wings of FIG. 6 extend part of the way around the darker gray or lighter gray space.

Thus because Gaudoin does not teach or suggest all the elements of amended claim 1, Gaudoin is not anticipatory. Claims 2 – 4, 6 – 9, 11, 12, and 22 depend from independent claim 1 and are also not anticipated by Gaudoin for at least the reasons presented above.

Further concerning claim 4

The Office Action maintains that the ‘inflatable members’ members of Gaudoin are tubular and have a circular cross section. This assertion is at odds with the assertion of the Office Action that the wings of Gaudoin are inflatable members. First, if, for the sake of argument, the wing is an inflatable member, it does not have a circular cross-section nor is it tubular. Second, if the three wings of Gaudoin make up a single inflatable member, it too, does not have a circular cross-section.

Claim 5 is patentable over Gaudoin

Claim 5 as amended, directed to a device for configuring an inflatable balloon, recites the presence of a plurality of independently inflatable members defining a channel. The independently inflatable members are inflatable inward to reduce the size of the channel. Other recitations are present in the claim as well.

Gaudoin does not disclose a plurality of independently inflatable members nor does Gaudoin disclose inflatable members which are inflatable inward to reduce the size of the channel. If the balloon of Gaudoin is inflated, the wings and the remainder of the balloon would extend outward, not inward. Moreover, the Gaudoin device for configuring a balloon does not have a plurality of inflatable members, let alone independently inflatable members, as discussed above with respect to claim 1.

Amended independent claim 5 is not anticipated by Gaudoin for at least the reasons presented above.

Claim 14 is patentable over Gaudoin

Independent claim 14 is directed to the *combination* of a device for configuring an inflatable balloon of a balloon catheter assembly *and* a balloon portion of a balloon catheter. The body of the device comprises a plurality of inflatable members defining a channel therebetween. The inflatable members are inflatable from a first size to a second size in which the inflatable members apply an inward force to a balloon of a balloon catheter assembly disposed in the channel. The balloon portion of a balloon catheter assembly is removably disposed in the channel. Other recitations are also present in the claim.

Gaudoin does not provide for at least the following recitations of the claim.

1. Gaudoin does not disclose a device for configuring an inflatable balloon where the device comprises the recited plurality of inflatable members. As discussed above, there is no disclosure in Gaudoin of using inflatable members for the dies.

2. Even if the balloon of the Gaudoin device were to be considered as the inflatable members, there is no balloon portion of a balloon removably disposed within the channel. The combination feature of the claim is not met. The balloon catheter of Gaudoin cannot be removably disposed within itself.

3. Even if the balloon of the Gaudoin device were to be considered as the inflatable members, they do not inflate inward. The Gaudoin balloon inflates outward.

Claim 25, and claim 26 which depends therefrom, are patentable over Gaudoin

Claim 25 is directed to a method of configuring at least a portion of a medical balloon. Claim 25 includes the steps of disposing a medical balloon between inflatable members; inflating the inflatable members inward toward the balloon so that the inflatable members deform portions of the medical balloon inward and at least partially deflating the medical balloon, the inwardly deformed portions of the medical balloon forming a plurality of balloon folds. Other recitations are present in the claim as well.

Gaudoin does not disclose at least the following steps:

1. Disposing a medical balloon between inflatable members. The only inflatable members disclosed in Gaudoin is the Gaudoin balloon. Gaudoin does not teach or suggest disposing a second balloon with the first balloon;

2. Inflating inflatable members inward toward the balloon so that the inflatable members deform portions of the medical balloon inward and at least partially deflating the medical balloon

At least for these reasons, claim 25, and dependent claim 26, are patentable over Gaudoin.

Claim 64, and claims 65 – 67 which depend therefrom, are patentable over Gaudoin

Claim 64 and its dependents are directed to a device for configuring an expandable member for use in a bodily vessel. The device comprises a plurality of inflatable members defining a channel therebetween. The inflatable members are inflatable inward so as to reduce in area a cross-section of the channel, the cross-section extending perpendicular to a longitudinal axis of the channel. Other recitations are present as well.

As discussed above, Gaudoin does not disclose inflatable members which are inflatable inward, let alone which are inflatable inward so as to reduce in area a cross-section of the channel, the cross-section extending perpendicular to a longitudinal axis of the channel.

The balloon of Gaudoin does not inflate inward, nor does it reduce in cross-section the channel extending through the Gaudoin balloon catheter.

Allowable Subject Matter

3. Claims 7 – 9, and claims 28 – 29 which depend on claim 7, have been found to contain allowable subject matter.

Conclusion

In light of the above comments, Applicant requests that the pending rejections be withdrawn and that the case be passed to allowance.

Respectfully submitted,

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